UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,997	07/26/2001	Donald W. Petersen	06317-038002	1532

7590 03/22/2002

ROBERT C. NABINGER
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER
WITZ, JEAN C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,997	Applicant(s) PETERSEN ET AL.	
	Examiner Jean C. Witz	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yim et al. (5,385,887).

The claims recite a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution and a plasticizing substance. The transitional phrase "consisting essentially of" is deemed to limit the scope of a claim to the specified components in the claims but also allows inclusion of "those [components] that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In this case, the prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic

(increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If Applicants contend that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). In this case, the instant specification teaches that other ingredients may be included with the claimed composition including demineralized bone matrix, bone morphogenic proteins and any number of other ingredients such as listed at page 4 of the specification. The composition of Yim et al. teaches a bone graft composition that contains calcium sulfate, specifically calcium sulfate hemihydrate, a mixing solution which may be water or a sodium chloride solution (among others), bone morphogenic proteins, a polymer matrix component to provide a scaffolding for the bone morphogenic proteins and what Yim et al. calls a "protein-sequestering material". This material is identical to what Applicants call their "plasticizing substance". The "protein-sequestering material" is included to "hold" the bone morphogenic protein at the site in need of the bone morphogenic protein, i.e. the site of the bone defect or injury. Basically, the "protein-sequestering material" acts to increases the viscosity of the composition thereby

reducing the rate of diffusion of the bone morphogenic proteins from the site of bone defect or injury but will also inherently act to "plasticize" the composition, i.e. give it a specific viscosity and flowability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al. (5,356,629) combined with Hanker et al. (4,619,655).

Sander et al. teach compositions for effecting bone repair that biocompatible particles dispersed in a matrix. The disclosed compositions have the benefit of effecting bone repair while possessing improved moldability, workability and other handling

characteristics upon being wetted with appropriate liquid medium. The matrix components disclosed by Sander et al. include cellulose ethers such as recited in claim 4 (see col. 2, lines 57-66). The matrix component may also be hyaluronic acid (as recited in claim 7 – see col. 2, lines 67-68). Sander et al. teach that the biocompatible particles may be bioresorbable or nonbioresorbable. While Sander et al. acknowledge in the Background of the Invention that plaster of paris (calcium sulfate hemihydrate) is known as a bioresorbable substance is conventionally used as a bone graft material, Sander et al. do not explicitly list calcium sulfate hemihydrate as a bioresorbable particle in the body of the patent specification.

Hanker et al. support the statements of Sander et al. that calcium sulfate hemihydrate is used as a resorbable bone implant. It is mixed with water and is applied to the damage or defect in the bone. The calcium sulfate hemihydrate, upon hydration, hardens in the area of implantation and acts both as a source of calcium for bone growth in the area of the implant, acts as a support for the damaged area during the time of repair, and stimulates revascularization and bone formation.

It would have been well within the skill and obvious to one of ordinary skill in the art at the time the invention was made to select calcium sulfate hemihydrate as the bioresorbable particle to be used in the formulation of the composition of Sander et al. Sander et al. provides a non-limiting list (the teaching of a U.S. patent is not limited to its recitations of preferred embodiments) and provides no proscription against its use. Insofar as the statements found at column 1, lines 30-34 of the Sander et al. patent are asserted be a teaching away from the use of calcium sulfate hemihydrate, it is clear

from the teaching of Hanker et al. at col. that resorbability of a calcium sulfate hemihydrate may be adjusted by adjusting the density of the calcium sulfate hemihydrate to obtain any desired resorption rate. Further, it is exactly the teaching of Sander et al. that motivates the addition of a matrix such as claimed to a calcium sulfate hemihydrate bone graft composition to improve the workability. With regard to the proscriptions of claims 12 and 13 against the inclusion of bone and a polymer matrix, since the compositions of both Hanker et al. and Sander et al. are disclosed as functional and suitable for the purpose of a bone graft composition, the practitioner would not need any further components. Finally, with regard to claims 14 and 15 which recite specific amounts of each component, it is noted that per claim 15, the calcium sulfate is present in an amount that comprises 72% of the composition, the plasticizing solution is present in an amount that comprises approximately 4% of the composition and the wetting solution is present in an amount that comprises 24% of the composition. Sander et al. teach that the bioresorbable component is present in the unwetted state from about 64 – 94% and that the matrix is present in the composition in the unwetted state from about 6 – 36% of the composition. After being wetted, the composition preferably comprises 35 – 75% bioresorbable component and the matrix preferably comprises 5 – 20% of the composition. Since the physical properties of both the calcium sulfate and the plasticizing (matrix) substances are well known and since the references teach that determining the desired time and degree of workability for the specific bone defect or damage is well within the skill of the practitioner, it would have equally been well within the skill of the practitioner at the time the invention was made to

engage in a reasonable and not undue amount of experimentation to determine a desired recipe for a bone graft composition containing calcium sulfate, a plasticizing substance as disclosed and the amount of wetting solution required, particularly since the amounts claimed are either well within the ranges disclosed or extremely close, as in the case of the ranges taught for the matrix component. It is also noted that the patent uses the term "about" which indicates that there is at least some leeway in the amounts taught to be effective.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 8 and 12-38 of copending Application No. 09/327761. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claims falls within the scope of the referenced claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jean C. Witz
Primary Examiner
Art Unit 1651

March 19, 2002